

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES  
INTERNATIONAL, INC. and ARIUS  
TWO, INC.,

Plaintiffs,

v.

ALVOGEN PB RESEARCH &  
DEVELOPMENT LLC, ALVOGEN  
MALTA OPERATIONS LTD., ALVOGEN  
PINE BROOK LLC, ALVOGEN, INC.,  
and ALVOGEN GROUP, INC.,

Defendants.

C.A. No. 18-1395 (CFC) (CJB)

~~PROPOSED~~ FINAL JUDGMENT

This action between Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. (collectively “BDSI”) and Defendants Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Inc., and Alvogen Group, Inc. (collectively “Alvogen”), having come to trial before the Court from March 1, 2021 to March 3, 2021, before the Honorable Colm F. Connolly, Chief Judge presiding, and the evidence and testimony of witnesses of each side having been heard and a decision having been rendered:

**IT IS ORDERED AND ADJUDGED** this 21<sup>st</sup> day of January, 2022, for the reasons set forth in the Court’s opinion dated December 20, 2021 (D.I. 300),

and the prior stipulation between the parties (D.I. 245, 246), that final judgment be and is hereby entered as follows:

1. Final Judgment is entered in favor of BDSI and against Alvogen on Counts I, III, IV, and VI, of BDSI's Complaint against Alvogen dated September 7, 2018 that by submitting Abbreviated New Drug Application ("ANDA") No. 211594 to the FDA, Alvogen has infringed, and if manufactured, used, marketed, offered for sale, or sold within the U.S. or imported herein, all dosage strengths of Alvogen's generic buprenorphine film product (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mg, 750 mcg and 900 mcg) would infringe claims 4 and 5 of U.S. Patent No. 8,147,866 ("the '866 patent"), and claim 9 of U.S. Patent No. 9,901,539 ("the '539 patent").

2. Final Judgment is entered in favor of BDSI and against Alvogen on Counts III and VI of BDSI's Complaint against Alvogen dated September 7, 2018, that by submitting ANDA No. 211594 to the FDA, Alvogen has infringed, and if manufactured, used, marketed, offered for sale, or sold, within the U.S. or imported herein, the 150 mcg dosage strength of Alvogen's generic buprenorphine film product would infringe claim 20 of the '539 patent.

3. Final Judgment is entered in favor of BDSI and against Alvogen that claims 4 and 5 of the '866 patent and claims 9 and 20 of the '539 patent are not invalid for the reasons set forth in the Court's Findings of Facts and Conclusions of Law on December 20, 2021 (D.I. 300).

4. Final Judgment is entered in favor of Alvogen and against BDSI on Counts II and V of BDSI's Complaint, dated September 7, 2018, that claims 8, 9, and 20 of U.S. Patent No. 9,655,843 ("the '843 patent") are invalid, and Final Judgment is entered in favor of Alvogen against BDSI that claims 3 and 10 of the '866 patent are invalid, for the reasons set forth in the Court's Findings of Facts and Conclusions of Law on December 20, 2021 (D.I. 300), and that Alvogen is thus not liable for infringement of these claims.

5. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of Alvogen's ANDA No. 211594 shall be a date no earlier than the December 21, 2032 expiration date of the '539 patent, which is the later to expire patent between the '866 and '539 patents, or later due to any extensions and/or additional periods of exclusivity to that date, except to the extent subsequently agreed between BDSI and Alvogen.

6. Alvogen shall notify the FDA in writing within five (5) days after entry of this final judgment (with a copy of such notice given simultaneously to BDSI) of this Court's decision that claims 4 and 5 of the '866 patent and 9 and 20 of the '539 patent are valid and that Alvogen's filing of ANDA No. 211594 infringes claims 4 and 5 of the '866 patent and claims 9 and 20 of the '539 patents as set forth above in paragraphs 1 and 2. ~~[BDSI Proposal: "and that the FDA should convert final~~

~~approval of ANDA No. 211594 to tentative approval.”] [Alvogen Proposal:~~

~~Alvogen does not agree with the inclusion of the underlined language.]~~

7. ~~BDSI Proposal:~~ [Pursuant to 35 U.S.C. § 271(e)(4)(B), Defendants and its officers, agents, servants, employees, successors, and attorneys, and those persons in active concert or participation with them, are enjoined, until the expiration of each of the '866 patent, and the '539 patent, from commercially manufacturing, using, selling or offering for sale in the United States, or importing into the United States Defendants' ANDA Products.]

~~Alvogen Proposal:~~ [Alvogen disagrees that Plaintiff BDSI's proposed paragraph 7 should be included.]

8. ~~BDSI Proposal:~~ [This Court retains jurisdiction to resolve Plaintiffs' Motion for an Order to Show Cause Why Defendants Should Not Be Held in Contempt for Violating the Court Order of June 28, 2021 (D.I. 282) as this motion is collateral to the merits of any appeal from the Court's Findings of Facts and Conclusions of Law on December 20, 2021, and should the Court grant Plaintiffs' Motion for an Order to Show Cause Why Defendants Should Not Be Held in Contempt for Violating the Court Order of June 28, 2021 (D.I. 282), the Court also retains jurisdiction over any accounting and awarding of damages or other appropriate relief as a result of such motion or under 35 U.S.C. § 271(e)(4)(C). See 28 U.S.C. § 1292(e)(2).]



~~**Alvogen Proposal – Option 1:** [Plaintiffs’ Motion for an Order to Show Cause Why Defendants Should Not Be Held in Contempt for Violating the Court Order of June 28, 2021 (D.I. 282) is dismissed without prejudice. All substantive issues have been fully adjudicated.]~~

~~**Alvogen Proposal – Option 2:**~~ [This Court retains jurisdiction to resolve Plaintiffs’ Motion for an Order to Show Cause Why Defendants Should Not Be Held in Contempt for Violating the Court Order of June 28, 2021 (D.I. 282) as this motion is collateral to the merits of any appeal from the Court’s Findings of Facts and Conclusions of Law on December 20, 2021, and should the Court grant Plaintiffs’ Motion for an Order to Show Cause Why Defendants Should Not Be Held in Contempt for Violating the Court Order of June 28, 2021 (D.I. 282), the Court also retains jurisdiction over any accounting and awarding of damages or other appropriate relief as a result of such motion or under 35 U.S.C. § 271(e)(4)(C). *See* 28 U.S.C. § 1292(c)(2). The Court finds that the invalidity and infringement determinations reached by the Court and stipulated by the parties (D.I. 245, 246, 300) are final and ripe for appeal. Alternatively, to resolve any jurisdictional issues, the Court also finds that entry of partial judgment under Federal Rule of Civil Procedure 54(b), set forth above, is warranted because there is no just reason for delay, the nature of the claims to be certified is such that no appellate court would have to decide the same issues twice, even if there are subsequent appeals, the claims

that are to be certified are separate from the claims that are pending, an immediate appeal is equitable, and judicial efficiency favors an immediate appeal. *See Curtis-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 9-10 (1980). The Court has considered the federal policy against piecemeal litigation and finds that the aforementioned factors outweigh this policy.]

9. Plaintiffs' claims for infringement of the unasserted claims of the '866, '843, and '539 patents in the Alvogen action shall be dismissed against Alvogen as moot.

10. In the event that any party appeals this Final Judgment, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within sixty (60) days after the issuance of the mandate from any such appeal.

11. In the event that no party appeals this Final Judgment, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within sixty (60) days after the expiration of the time for filing a notice of appeal under Federal Rules of Appellate Procedure 3 and 4.

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*Attorneys for Defendants*

IT IS SO ORDERED this 21<sup>st</sup> day of January, 2022.

  
CHIEF UNITED STATES DISTRICT JUDGE